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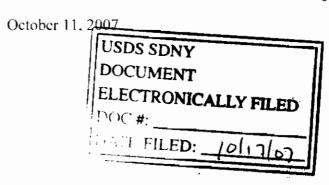
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BY HAND

The Honorable Richard J. Sullivan United States District Court Southern District of New York 500 Pearl Street Room 615 New York, New York 10007



Re: The Procter & Gamble Company v. Ultreo, Inc., Case No. 07 Civ. 8379 (RJS)

Dear Judge Sullivan:

We are counsel to The Procter & Gamble Company ("P&G") in the above-referenced case, which was reassigned to your Honor on October 10, 2007. Pursuant to your Honor's Individual Praetices, we are writing to request a pre-motion conference with the Court so that P&G may file a motion seeking a preliminary injunction pursuant to Federal Rule of Civil Procedure 65.

P&G commenced this action against Ultreo, Inc. ("Ultreo") on September 27, 2007 asserting claims under the federal Lanham Act, 15 U.S.C. § 1125 *et seq.* and the New York Consumer Protection Act, N.Y. Gen. Business Law §§ 349(a), 349(h), 350, 350(a) and 350(e). P&G's complaint alleges that Ultreo has, and continues to be, engaged in a false and deceptive advertising campaign related to its "Ultrasound" toothbrush. In its complaint, P&G seeks injunctive relief, as well as damages.

P&G contends that Ultreo's advertising campaign contains a number of false and misleading claims. Specifically, Ultreo claims that its "groundbreaking" ultrasound feature and its "pulsating bubbles" can remove plaque bacteria when used by a consumer. Ultreo refers to the ultrasound feature as "magic." These claims are false because recently conducted tests by P&G and by another competitor. Philips Oral Healthcare, Inc., show that the ultrasound feature has no effect on plaque removal or teeth cleaning in actual use. Ultreo is apparently basing these claims on *in vitro* studies (studies conducted in an artificial environment, such as a petri dish), which do not accurately predict how the Ultreo brush and the ultrasound feature will perform in a

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user's mouth. Courts have uniformly rejected and enjoined advertising claims that are based only on *in vitro* studies that can not be replicated in actual use.

Prior to commencing this action, P&G asked Ultreo for its support for its advertising claims, and specifically for the *in vivo* (i.e., actual human use studies) necessary to support such claims. When it became clear that Ultreo had no actual basis for the claims, P&G asked that they be modified. Although Ultreo made several minor modifications to its advertising campaign, it declined to make any additional changes to correct its false messages and has continued making claims about the ultrasound feature's ability to remove plaque bacteria.

When P&G's efforts to have Ultreo modify the claims were finally rejected by Ultreo, P&G proceeded to conduct two studies to demonstrate their false and misleading nature.

First, P&G conducted a clinical *in vivo* study – testing the Ultreo toothbrush in the mouths of actual users – which confirmed that Ultreo's *in vitro* test was not an accurate predictor of how the Ultreo toothbrush would perform in actual use. P&G's clinical study revealed that there was no meaningful difference between using the ultrasound feature of the Ultreo toothbrush and simply swishing toothpaste around one's mouth. P&G's clinical study further concluded that turning off the Ultreo toothbrush and using it as a manual toothbrush actually removed more plaque than using the Ultreo toothbrush – with its ultrasound waveguide operational – as instructed. P&G's clinical study demonstrates that the ultrasound component of the Ultreo brush does not provide any plaque removal benefit. P&G has provided Ultreo with a copy of the results of this clinical study. (Moreover, as indicated above, Philips recently released a study with similar conclusions.)

Second, P&G commissioned a consumer survey in order to assess consumer understanding of Ultreo's advertising claims. Earlier this week, P&G received the results of this study, which showed that an overwhelming percentage of consumers are being deceived into believing that the ultrasound technology, and the bubbles Ultreo claims it activates, are able to clean their teeth alone (*i.e.*, without any bristle action). Seventy-two percent of the consumers concluded after viewing Ultreo's advertisements that the ultrasound alone would clean their teeth, or clean their teeth better. Forty-eight percent of the consumers believed that ultrasound

Is a smithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co., 906 F. Supp. 178 (S.D.N.Y. 1995): (finding a claim that TUMS ULTRA began to work within seconds false because although clinical pH studies showed that TUMS had an almost immediate effect on pH levels of gastric acid in the lab, test conducted in actual stomach conditions proves TUMS took between 1.3 and 42 minutes to raise pH levels in the stomach). See also Church & Dwight Co. v. S.C. Johnson & Son, Inc., 873 F. Supp. 893, 903 (D.N.J. 1994) (holding that a baking soda manufacturer's claims about odor absorption literally false where in in vitro tests could not be correlated to in vivo tests); United States v. Premo Pharm. Labs. Inc., 511 F. Supp. 958, 985-86 (D.N.J. 1981) (explaining in a case alleging violations of the Federal Food, Drug, and Cosmetic Act "[i]n vitro tests do not provide a basis for conclusions . . . unless a correlation has been made between the results of those studies and the results of an in vivo study").

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alone would clean their teeth better than without ultrasound. These results confirm the deceptive nature of Ultreo's advertising campaign.

Now that P&G has collected the above evidence to support its request for injunctive relief, it wishes to seek a preliminary injunction to stop Ultreo's on-going false and misleading advertising campaign. Additionally, P&G is prepared to submit evidence to demonstrate that it is being injured as a result of Ultreo's false and misleading advertising campaign. Injunctive relief is necessary to prevent further consumer deception and harm to P&G. Moreover, the risk of injury to the public, specifically their dental health, justifies the issuance of an injunction.

Finally, P&G is seeking preliminary relief at this time in light of the upcoming holiday shopping season. As with many products, the holiday season is an important time for the sales of power toothbrush sales. P&G estimates that nearly forty percent of Oral-B premium power toothbrush sales occur in the months of October, November and December. As a result, a preliminary injunction is necessary to protect P&G during this critical period.

We are available for a pre-motion conference at any time.

Respectfully submitted.

Theresa M. Gillis

Counsel for Procter & Gamble

cc: Marc C. Levy, Counsel to Ultreo

Premotion conference set to October 24,2007 @ 3:30pm.

RICHARD J. SULLIVAN

U.8.D.J.

NY1-4031516v1

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October 16, 2007

BY HAND

The Honorable Richard J. Sullivan United States Courthouse 500 Pearl Street – Room 615 New York, New York 10007

Re: Proctor & Gamble v. Ultreo, Inc., Case No. 07 Civ. 8379 (RJS)

Dear Judge Sullivan:

We represent Ultreo, Inc. ("Ultreo") and respond, pursuant to Your Honor's Individual Rules, to Ms. Gillis' letter of October 11.

With respect to P&G's proposed motion for a preliminary injunction, we respectfully request that the filing of Ultreo's opposition papers be deferred until after it has had an opportunity to conduct certain discovery it needs.

Ultreo was formed in 2003 by former executives and scientists of Optiva Corporation ("Optiva"), the creator and original manufacturer of the Sonicare brand power toothbrush. Optiva was ultimately acquired by Philips Electronics. The Sonicare brand has the second largest share, after P&G's Oral-B brand, in the market for premium power toothbrushes.

Ultreo, working with dental and ultrasound experts from the University of Washington and having received two grants from the National Institutes of Health, has developed a new power toothbrush that combines sonic bristle action with ultrasound technology. Ultrasound as a cleaning technology is not new. To the contrary, ultrasound activated bubbles have been used for years to clean jewelry and surgical instruments, among many other cleaning applications. The novelty of the Ultreo is the incorporation of an ultrasound waveguide in a home oral care appliance. The U.S. Patent & Trademark Office has recognized that novelty by granting Ultreo a patent on the ultrasound technology incorporated in the Ultreo toothbrush.

Ultreo has conducted several clinical research studies establishing that the Ultreo brush is safe and effective in removing plaque bacteria, reducing gingivitis (gum disease) and removing stains on teeth. The Ultreo brush has also been clinically proven to outperform a manual toothbrush with respect to hard-to-reach plaque. P&G does not and cannot dispute these results. Instead, P&G claims that Ultreo should have a clinical study that isolates the plaque removal

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capabilities of each of the two mechanisms of the Ultreo brush — the sonic bristle action and the ultrasound technology. Yet, no industry standard or legal authority requires companies to cite clinical studies to support claims regarding the efficacy of oral health products, let alone the various components of such products. Indeed, the evidence will show that both P&G and Philips, the two market leaders, currently make claims regarding the cleaning capabilities of oral care products based solely upon laboratory studies.

There is no urgency in this case and no reason to deprive Ultreo of its right to take discovery regarding facts that are relevant to P&G's motion. In light of the unquestioned safety and efficacy of the Ultreo product, no risk of "injury" exists to the public's "dental health." The only risk is that P&G's monopolistic market share will be threatened by legitimate competition. See Procter & Gamble Pharms., Inc. v. Hoffman-La Roche, Inc., 2006 WL 2588002 at *10 (S.D.N.Y. Sept. 6, 2006) (Crotty, J.) (observing in a false advertising case that "P&G's chief concern is not public health and safety, but rather its market share"). And, as for that risk, it is minimal. Ultreo's sales to date (approximately \$3 million), pale in comparison to Oral-B's annual sales of over \$1 billion last year. No factual basis exists for P&G to argue that Ultreo's sales during this case will have a material impact on Oral-B's sales. Id. at *10 (commenting that P&G's motive in seeking to enjoin a competitor's advertising was to stop a potential new market entrant in "the starting blocks"). Indeed, P&G waited more than six months to file its motion after it advised Ultreo of its objections to Ultreo's advertising.

Although we have not seen P&G's moving papers, based on its letter, there are at least two areas of discovery that Ultreo needs to conduct to respond to the motion.²

First, P&G claims it has conducted a clinical study that establishes that Ultreo's ultrasound technology cannot remove plaque. It has produced only a two-page summary abstract of the study. We have not seen the protocol, the underlying test data, or the statistical analysis of the test results. Nor do we know how the subjects were selected or what brushing instructions they received.

Based on the limited information provided, the study was not designed to isolate and test the ultrasound mechanism of the Ultreo brush. Instead, P&G tested the brush with the power on

The cases cited by P&G do not support its hyperbolic contention that courts have "uniformly rejected" advertising claims based on *in vitro* studies. Even in cases involving product superiority claims, the plaintiff bears the burden of demonstrating that Ultreo's tests are "not sufficiently reliable to permit one to conclude with reasonable certainty that they established the proposition for which they were cited." *P&G Co. v. Chesebrough-Pond's, Inc.,* 747 F.2d 114, 119 (2d Cir. 1984). This inquiry does not lend itself to any hard-and-fast rule. As the Second Circuit noted in *Chesebrough-Pond's,* "[t]he fact-finder's judgment should consider all relevant circumstances, including the state of the testing art [for the product at issue], the existence and feasibility of superior procedures, the objectivity and skill of the persons conducting the tests, the accuracy of their reports, and the results of other pertinent tests." *Id.* at 119.

District courts in this Circuit frequently permit discovery in connection with motions for preliminary injunctive relief. See, e.g., Revton Consumer Prods. Corp. v. Jennifer Leather Broadway, Inc., 858 F. Supp. 1268, 1269 (S.D.N.Y. 1994), aff'd, 57 F.3d 1062 (2d Cir. 1995); Guardsmark, Inc. v. Pinkerton's, Inc., 739 F. Supp. 173, 174 (S.D.N.Y.), aff'd, 923 F.2d 845 (2d Cir. 1990).

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(employing both the sonic bristle and ultrasound technologies) and the power off (employing neither technology). Moreover, the study purports to conclude that Ultreo functions better as a manual toothbrush than as a power toothbrush. This conclusion contradicts Oral-B's own industry research findings. As P&G's Oral-B Research Director Paul Warren has observed, there is a "wealth of data from controlled clinical studies which demonstrates greater effectiveness of electric toothbrushes over manual brushes." Warren P.R., et al., JADA 2000:131:389-94.

A second area of discovery concerns a consumer study that P&G has apparently commissioned. P&G has not provided this study to Ultreo and Ms. Gillis' letter is devoid of any details regarding that study, including the Ultreo ads tested, the survey methodology employed, or the participants involved.

Significantly, the claim that the ultrasonic technology of the Ultreo can remove plaque bacteria (as shown in laboratory studies) is currently being made in advertising that is directed towards dental professionals — not consumers. Dental professionals, consisting of dentists and dental hygienists, are a sophisticated and knowledgable audience that is more than capable of reviewing Ultreo's publicly-available clinical and laboratory research reports and forming their own opinions as to the merits of Ultreo's claims. Discovery would reveal whether ads directed to professionals were tested with consumers, which would tend to invalidate the study as a reliable predictor of consumer reaction to the different set of ads directed to consumers.

Moreover, two of the Ultreo ad claims quoted in Ms. Gillis' letter, regarding "groundbreaking" technology and "magic," are plainly examples of non-actionable puffery under the law of this Circuit. See Time Warner Cable, Inc. v. DIRECTV, Inc., 497 F.3d 144, 159-61 (2d Cir. 2007) (subjective claims and exaggerations are not actionable under the Lanham Act). Indeed, P&G itself claims to consumers that its products represent "the next generation" in power toothbrushes and are "amazing." Discovery is needed to ascertain whether consumer responses were influenced by claims that cannot be challenged under the Lanham Act.

We are prepared to discuss these issues at a conference at Your Honor's convenience.

Respectfully,

Anthony DiSarro

cc: Theresa M. Gillis, Esq.
Counsel to Proctor & Gamble
(By Electronic Mail and Fed Ex Priority Overnight)